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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,131	02/01/2002	John C. Russell	6885.US.O1	2508

23492 7590 11/20/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/20/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,131

Applicant(s)

RUSSELL, JOHN C.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 19, 20, 26 and 27, drawn to a method of making a suspended or soluble protein conjugate and the products produced by the method, classified for example, in class 530, subclass 402.
- II. Claims 2-18, drawn to a method of making a suspended or soluble macromolecular conjugate, classified for example, in class 435, subclass 7.92.
- III. Claims 21 and 22, drawn to antibody conjugates, classified for example, in class 530, subclass 391.3 and class 514.
- IV. Claim 23, drawn to a three-dimensional surface comprising three layers of macromolecules, classified for example, in class 436, subclass 530.
- V. Claim 24, drawn to a conjugate comprised of a specific binding member and an end-point molecule, classified for example, in class 436, subclass 500.
- VI. Claim 25, drawn to a population of conjugates on a surface, classified for example, in class 530, subclass 391.5.
- VII. Claims 28 and 29, drawn to a kit comprising a solid bonded with a first macromolecule covalently complexed with a reactive macromolecule, classified for example in class 435, subclass 7.5.

2) The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require the use of functionally and chemically different components.

For example, the method of making the "suspended or soluble protein conjugates" of Invention I requires the use of a "protein" component and a "Second Molecule" (type/function unspecified) component in a sequence of method steps a) - e) (see claim 1) while the conjugates of Invention II

Art Unit: 1641

require a "First Macromolecule" (type/function unspecified) component and a "Second Molecule" (type/function unspecified) component in a different sequence of steps a) – f) (see claim 2).

The antibody conjugates of Invention III do not require the same components required by any other invention. The same is true for the conjugates of Inventions IV-VII. For example, the "reactive conjugate complex" and "cleavage reagent" components of the kit of Invention VII do not correspond with the components used in either Invention I or Invention II. The three-dimensional surface of Invention IV requires none of the particulars of any other invention. Similarly, the conjugate comprised of "a specific binding member" and "end-point molecules" of Invention V has different components than all of the other inventions. See also, the conjugate of Invention VI which requires neither the solid-surface of Invention I (see claim 26) nor a specific method of preparation (see product by process claim 26).

3) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, requiring divergent fields of search and different patentability considerations, restriction for examination purposes as indicated is proper.

4) The claims are generic to a plurality of disclosed patentably distinct species which define patentably distinct inventions. For example, different combinations of species defined as "first macromolecule", "second macromolecule", "bifunctional linker", "third macromolecule", "residual reactive moiety", "conjugates", "chromophore", "reactive molecule", "population of conjugates", etc. define patentably distinct inventions. For the election of any one of Inventions I-VII, applicant is required under 35 U.S.C. 121 to elect a single disclosed species defined by electing a single species of each recited variable, even though this requirement is traversed. For example, for the election of Invention II, an election of species must be made of a "first macromolecule", "second macromolecule", "stable, disruptable bond", "bifunctional linker" (claim 4), "third macromolecule", and "capping compound". The

Art Unit: 1641

claims will be examined on the merits to the extent that they encompass the elected invention/species and all other combinations of species which are patentably indistinct from the elected invention.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

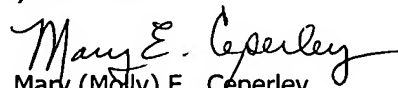
5) Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

November 18, 2003


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641